Supreme Court, U. S.
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In The

Supreme Court of the United States

October Term, 1978

No. 78-1725

UNITED STATES OF AMERICA,

Respondent,

vs.

ARTICLES OF FOOD, ETC., ROBERT NIELSEN d/b/a GRUMPY'S BUFFALO JERKY CO.,

Petitioner.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

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UNITED STATES OF AMERICA,

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—o—

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

—o—

Robert Nielsen d/b/a Grumpy's Buffalo Jerky Co., Petitioner herein, respectfully prays that a writ of Certiorari issue to review the judgment and opinion of the United States Court of Appeals for the Eighth Circuit (Court of Appeals) entered in these proceedings on January 16, 1979.

OPINIONS BELOW

The opinion of the District Court for the District of Nebraska (District Court) is reported at 456 F. Supp. 207 (D. Neb. 1978) and is reproduced in Appendix A hereto along with the District Court's unreported order. The opinion of the Court of Appeals is unreported but is reproduced in Appendix B hereto.

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JURISDICTION

The judgment of the Court of Appeals was entered on January 16, 1979. The time for filing a Petition for Certiorari was extended to May 16, 1979, by order of Mr. Justice Blackmun dated April 13, 1979. The jurisdiction of this Court is invoked under 28 U. S. C. Section 1254 (1).

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QUESTIONS PRESENTED

1. Whether the Court of Appeals in affirming the judgment of the District Court erred in concluding that the food product involved in the case at bar is adulterated within the meaning of 21 U. S. C. Section 342 (a)(2)(c) for the reason that said food product contains food additives as defined in 21 U. S. C. Section 321 (s), to-wit, sodium nitrate and sodium nitrite.

2. Whether the Court of Appeals in affirming the judgment of the District Court erred in concluding that

bison meat is not within the purview of the Meat Inspection Act, 21 U. S. C. Section 601 et. seq.

3. Whether the Court of Appeals in affirming the judgment of the District Court erred in holding that sodium nitrate and sodium nitrite are not generally recognized as safe in conjunction with processing bison meat.

—o—

STATUTORY PROVISIONS INVOLVED

1. Federal Food, Drug and Cosmetic Act, 21 U. S. C. Section 301 et. seq. Pertinent provisions of this statute are set forth in Appendix C, *infra*.

2. Meat Inspection Act, 21 U. S. C. Section 601 et. seq. Pertinent provisions of this statute are set forth in Appendix C, *infra*.

—o—

MISCELLANEOUS

1. 9 C. F. R. Section 301 et. seq. Pertinent provisions of these regulations are set forth in Appendix C.

—o—

STATEMENT OF THE CASE

Respondent initiated this action to seize and condemn certain food products as being adulterated pursuant to the Federal Food, Drug and Cosmetic Act (herein called "Act"), 21 U. S. C. Section 301 et. seq. Respondent alleged

that the food product, commonly known as "Buffalo Jerky" was adulterated within the meaning of the Act, 21 U. S. C. Section 342 (a)(2)(c), and 21 U. S. C. Section 342(b)(2) in that the food product "Buffalo Jerky" contained ingredients, to-wit, sodium nitrate and sodium nitrite, and that plant proteins, textured vegetable protein and hydrolyzed vegetable protein, as well as water and monosodium glutamate, were substituted for buffalo (bison) meat. Respondent further alleged that the food product, "Buffalo Jerky" was misbranded within the meaning of the Act, 21 U. S. C. Section 343 (i)(1), in that the names "Buffalo Jerky" and "Buffalo Chips" was not the common or usual name for a product composed of buffalo meat (bison), water, plant proteins, preservatives, and other ingredients.

Petitioner intervened in the proceeding by filing a claim for the food product. Both Respondent and Petitioner moved for summary judgment. The District Court, pursuant to a stipulation of fact and affidavits, sustained Respondent's motion for summary judgment and overruled Petitioner's motion for summary judgment.

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STATEMENT OF FACTS

The parties stipulated that there existed at York, Nebraska, in possession of Petitioner, food products consisting of dark brown colored patties with the following ingredients: buffalo (bison) meat, textured vegetable proteins, hydrolyzed vegetable proteins, salt, spices, flavorings, sodium erythorbate, sodium nitrate, sodium nitrite, potassium sorbate, as well as water and monosodium glutamate,

and bearing the names "Buffalo Jerky" and "Buffalo Chips".

———o———

PROCEEDINGS BELOW

Respondent commenced this lawsuit by filing a complaint for forfeiture in the District Court on October 3, 1978, seeking condemnation of the food product "Buffalo Jerky". Petitioner intervened in the litigation and filed an answer denying the allegations in Respondent's complaint.

On the basis of the stipulation of fact and accompanying affidavits, the District Court entered an Order on July 12, 1978, sustaining Respondent's motion for summary judgment and denying Petitioner's motion for summary judgment.

In a memorandum of decision accompanying the order (see Appendix A) the District Court first found that sodium nitrate and sodium nitrite were "food additives" within the meaning of 21 U. S. C. Section 321 (s).

The District Court next determined that bison meat is not within the purview of the Meat Inspection Act, 21 U. S. C. Section 601 et. seq.

Finally, the District Court determined that sodium nitrate and sodium nitrite, being food additives within the meaning of 21 U. S. C. Section 342 (a)(2)(c), were unsafe within the meaning of 21 U. S. C. Section 348. The District Court concluded that the food product was adulterated

within the meaning of 21 U. S. C. Section 342 (a)(2)(c) and thus subject to seizure and condemnation.

The District Court having determined that the food products were adulterated did not reach the Respondent's alternative allegation of adulteration and misbranding.

The Court of Appeals concluded that the District Court did not err, and affirmed the judgment on the basis of the District Court's opinion. The destruction of the food product has been stayed pending resolution of this Petition for Certiorari.

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REASONS FOR GRANTING THE WRIT

I.

This Court should issue a writ of certiorari to decide whether sodium nitrate and sodium nitrite are food additives within the definition of 21 U. S. C. Section 342 (a) (2) (c).

The District Court concluded that sodium nitrate and sodium nitrite were food additives within the definition of 21 U. S. C. Section 321 (s), and thus the food product which contained them was adulterated pursuant to 21 U. S. C. Section 342 (a)(2)(c).

Sodium nitrate and sodium nitrite (commonly known as salt) have been used since time immemorial to cure meats and poultry. Reference to the use of nitrates can be traced back several hundred years and continued after passage of the Federal Meat Inspection Act. See 9

C. F. R. 318, 1975. There can be no doubt that sodium nitrate and sodium nitrite have been an effective tool in preventing the development of botulism in meat and poultry products. 9 C. F. R. 318, 1975.

Under 21 U. S. C. Section 342 (a)(2)(c), a food product is adulterated if it bears or contains any food additive. "Food Additive" is defined in 21 U. S. C. Section 321 (s) as a substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any Food, but does not include any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to the Meat Inspection Act of March 4, 1907, as amended or extended.

This is apparently a question of first impression and therefore requires a definitive determination by this Court.

The District Court concluded, albeit erroneously, that the specific use of the substances sodium nitrate and sodium nitrite in bison meat must have been sanctioned by the Meat Inspection Act, 21 U. S. C. Section 601 et. seq. in order to come with the exception contained in 21 U. S. C. Section 321 (s) (4). The language of 21 U. S. C. Section 321 (s) (4) is clear in stating that a food additive does not include *any substance* used in accordance with a sanction or approval granted pursuant to the Meat Inspection Act of March 4, 1907, as amended and extended. It is not the food product to which the food additive is added that must have been approved under the Meat Inspection Act, 21 U. S. C. Section 601, et. seq., but the *substance*. The substances in the case at bar are sodium nitrate and sodium nitrite, not the food product "Buffalo Jerky".

The use of sodium nitrate and sodium nitrite have been specifically sanctioned and approved under the Meat In-

spection Act, 21 U. S. C. Section 601, et. seq. Regulations issued under the Act, 9 C. F. R. Section 318.7 (c)(10) state *inter alia*:

> . . . the following substances may be added to products: common salt, approved sugars. . . sodium nitrate, sodium nitrite, potassium nitrate, potassium nitrite. . .

It is at this point that the question of sodium nitrate and sodium nitrite being food additives must be determined. The District Court, however, concluded that in order for sodium nitrate and sodium nitrite to not be food additives, further analysis must be made of the food product itself, to-wit, "Buffalo Jerky". This conclusion does not find support in the specific language of 21 U. S. C. Section 321 (s)(4), which only mandates that the "substance" must be used with approval under the Meat Inspection Act, 21 U. S. C. Section 601, et. seq. There is no limitation contained in 9 C. F. R. Section 318.7 (c)(10) governing the use of sodium nitrate and sodium nitrite. The interpretation advanced by Petitioner finds implicit support in *United States of America v. Naremco, Inc.*, 553 F. 2d 1138 (8th Cir. 1977). In this case, the Court in discussing whether a substance was a food additive within 21 U. S. C. Section 321 (s), limited its discussion to the substance involved and not the product to which the substance was added. This interpretation is consistent with the tenor of 21 U. S. C. Section 321 (s). The District Court erred in judicially broadening the definition of food additive as contained in 21 U. S. C. Section 321 (s).

Petitioner's position is further buttressed by reference to the Meat Inspection Act, 21 U. S. C. Section 601 et. seq. Under 21 U. S. C. Section 601 (m)(2)(c), a product

is adulterated "if it bears or contains any food additive which is unsafe within the meaning of Section 348 of this title". In other words, if a substance is declared a food additive as defined in 21 U. S. C. Section 321 (s), then pursuant to 21 U. S. C. Section 348, the substance will then render the meat or meat food product to which it is added adulterated within 21 U. S. C. Section 601 (m)(2)(c).

This statutory relationship between the Act and the Meat Inspection Act fully supports Petitioner's position that sodium nitrate and sodium nitrite are not food additives. In *Chip Steak Co. v. Hardin*, 332 F. Supp. 1084 (D. C. M. D. Cal. 1971) the Court stated:

> The legislative history of the Federal Meat Inspection Act, as amended, *supra,* indicates that by the above provision Congress intended to allow the Secretary of Agriculture to impose more stringent restrictions . . . for food additives . . . in or on meat products subject to the new act than are imposed by the Secretary of Health, Education, and Welfare under the Federal Food, Drug and Cosmetic Act. 322 F. Supp. at 1089.

A number of food products available for human consumption contain sodium nitrate and sodium nitrite, and said products bear the seal "U. S. inspected and passed by Department of Agriculture Est. 2862". Obviously these products are not adulterated under the Meat Inspection Act; however, they do contain sodium nitrate and sodium nitrite. The only explanation for the products not being adulterated is that they do not contain food additives, since a product containing food additives is adulterated under 21 U. S. C. Section 601 (m) (2) (c).

According to the District Court, sodium nitrate and sodium nitrite are food additives. Following this reason-

ing to its logical conclusion would render all products on the market today containing either/or sodium nitrate or sodium nitrite as adulterated, and thus unfit for human consumption. A substance cannot be a food additive in a certain context, and not be a food additive in another context. The term "food additive" is contained both in the Act and the Meat Inspection Act. Both the Act and the Meat Inspection Act are primarily directed at protecting the health and welfare of consumers. In *Northcross v. Board of Education of Memphis City Schools*, 412 U. S. 427, 37 L. Ed. 2d 48, 93 S. Ct. 2201 (1973), the Court stated that statutes containing similar language and sharing common raison d'etre should be interpreted pari passu. Futher, in *Erlenbaugh v. U. S.*, 409 U. S. 239, 34 L. Ed. 446, 93 S. Ct. 477 (1972), the Court stated that the concept "in pari materia" is a reflection of practical experience in interpreting statutes: a legislative body generally uses particular words with consistent meaning in a given context. If the District Court's analysis is correct, then food additives are being treated differently under the Act than under the Meat Inspection Act, and this is contrary to the well established tenets of statutory construction.

In order for the food product "Buffalo Jerky" to be adulterated within 21 U. S. C. Section 342 (a)(2)(c), a food additive must be unsafe. However, if the food product does not contain a food additive in the first place, as in the case at bar, the question of safe or unsafe within 21 U. S. C. Section 342 (a) (2) (c) becomes moot. Since sodium nitrate and sodium nitrite are not food additives, being within the purview of 21 U. S. C. Section 321 (s) (4), the food product in which they are contained cannot be adulterated under 21 U. S. C. Section 342 (a) (2) (c).

It is important that this Court resolve the apparent inconsistent treatment afforded to a substance under the Act and the Meat Inspection Act, and determine when a substance is or is not a food additive. The current public controversy surrounding sodium nitrite and sodium nitrate further supports the necessity for this Court to review this matter.

II.

This Court should issue a writ of certiorari to decide the relationship and jurisdiction of the Food and Drug Administration and Department of Agriculture over bison meat.

The Court of Appeals affirmed the District Court's conclusion that bison meat is not within the purview of the Meat Inspection Act, 21 U. S. C. Section 601 et. seq. However, the regulating definitions contained in 9 C. F. R. Section 301.2 et. seq. make it clear that bison meat was included therein. Clearly, if bison meat is indeed within the regulatory scheme of the Meat Inspection Act, 21 U. S. C. Section 601 et. seq., the use of sodium nitrate and sodium nitrite is specifically authorized, 9 C. F. R. Section 318.7 (c)(10), thus exempting them from the definition of food additives contained in 21 U. S. C. Section 321 (s) and precluding a determination that the product is adulterated within the meaning of 21 U. S. C. Section 342 (a) (2) (c).

The statutory scheme of the Meat Inspection Act, 21 U. S. C. Section 601 et. seq. is designed to protect the health and welfare of consumers by assuring that meat and meat food products distributed to them are wholesome. The Meat Inspection Act creates a separate area of concern by

which the Department of Agriculture can impose more stringent restrictions than under the Act, *Chip Steak Co., supra.*

The Meat Inspection Act regulates foods derived from cattle, sheep, swine, goats and equines. When the meaning of a word in a statute is not clear from the statute itself, recourse may be made to the dictionary. *United Shoe Workers of America AFL-CIO v. Bedell*, 506 F. 2d 174 (D. C. Cir. 1974). *Webster's Third New International Dictionary* (1966) defines an equine as an animal resembling a horse. Does not a bison (buffalo) resemble a horse? Clearly a buffalo is within the definition of equine.

At the time the Meat Inspection Act was adopted, the re-emergence of bison meat as a viable and less expensive alternative to other meats had not commenced. Today, the inexpensive substitute of bison meat and "beefalo" are realities. To conclude that bison meat was not intended within the regulatory scheme of the Meat Inspection Act begs the question. This situation was faced by the Court in *Investment Annuity, Inc. v. Blumenthal*, 442 F. Supp. 681 (D. D. C. 1977), where the Court stated:

> The mere fact that Congress did not consider an as yet uninvented alternative to a 'statutorily approved' arrangement cannot be said to bar application of the statute to a later-invented alternative if that alternative is comparable to the 'approved arrangement' in substantially all respects. Defendant's construction ignores the generally-accepted canon of statutory construction that where Congress has made a choice of language which fairly brings a given situation within a statute, it is unimportant that the particular application may not have been contemplated by the legislators. 442 F. Supp. at 689.

This Court was faced with a similar question in *Fortnightly Corp. v. United Artists Television*, 392 U. S. 390, wherein the question of copyright infringement by community antenna television systems was addressed. The community television system had not been envisioned by congress when the copyright statutes had been drafted—but statutes must be read in light of technological change. This Court cited, with approval, the following language from *Jerome H. Remick and Co. v. American Automobile Accessories Co.*, 5 F. 2d 411 (6th Cir.):

> 'While statutes should not be stretched to apply to new situations not fairly within their scope, they should not be so narrowly construed as to permit their evasion because of changing habits due to new invention and discoveries.' 392 U. S. at 395.

The fact that bison meat was not specifically included in the Meat Inspection Act is of no consequence. The maxim, *expressio unius est exclusio alterium* is increasingly considered unreliable since it stands on the faulty premise that all possible alternatives or supplemental provisions were necessarily considered and rejected by the legislative draftsmen. *National Petroleum Refiners Association v. FTC,* 482 F. 2d 672 (D. C. Cir. 1971).

Congress intended by the Meat Inspection Act to authorize the Department of Agriculture to assure that meat and meat by-products would be wholesome. It is anomalous that sodium nitrate and sodium nitrite are allowed to be added to meat and meat byproducts under the stricter auspices of the Department of Agriculture, but not under the Food and Drug Administration. Petitioner submits that bison meat is, and should be regulated under the Meat Inspection Act, and that sodium nitrate and sodium

nitrite should be exempt from the definitions of food additive contained in 21 U. S. C. Section 321 (s). The excellence of our jurisprudences is its flexibility to adapt to change. Does the decision of the Court of Appeals mean that if a new meat product was developed not within the statutory guidelines of the Meat Inspection Act, 21 U. S. C. Section 601 et. seq. it would not be regulated by the Department of Agriculture under the Meat Inspection Act. We think not.

This Court should review this case to clearly delineate what foods come under the jurisdiction of the Department of Agriculture and which come under the jurisdiction of the Food and Drug Administration, with particular emphasis on bison meat. A substance should not be a food additive under one federal agency and not a food additive under another federal agency. The only casualty from this inter-agency battle is Petitioner who is placed in a noncomplying situation by the disparate treatment of federal agencies.

III.

This Court should issue a writ of certiorari to review the Court of Appeals' holding that sodium nitrate and sodium nitrite are not generally recognized as safe in conjunction with processing bison meat.

This District Court, relying on the conclusory affidavits of Samuel I. Shibko and Richard J. Ronk, concluded that sodium nitrate and sodium nitrite were not generally recognized as safe in conjunction with the processing of bison meat. The primary use of both sodium nitrate and sodium nitrite is a preservative to prevent botulism. The use to which sodium nitrate and sodium nitrite are put in the case at bar is identical.

Sodium nitrate and sodium nitrite have been specifically recognized for use in the curing of certain products, 9 C. F. R. Section 318.7 (c)(10), 21 C. F. R. Section 172.175 and 21 C. F. R. Section 172.170. In addition, the Department of Agriculture has approved the use of sodium nitrate and sodium nitrite in the curing and preserving of products. In *Schuck v. Butz*, 500 F. 2d 810 (D. C. Cir. 1974), the Court stated:

> On March 16, 1972, Assistant Secretary Richard Lyng responded to the Petition in a letter which stated that the Department would not immediately prohibit all use of nitrates in meats. He asserted that there was no convincing evidence that the addition of nitrates to meat would result in an adulterated product. He also pointed to evidence that the addition of nitrates may reduce the dangers of botulism in meat products, and suggested that a ban on nitrates would eliminate this benefit, perhaps unnecessarily . . . Addition of sodium nitrate or sodium nitrite within the limits specified in the regulation, would not result in a product that is hazardous to human health. 500 F. 2d at 811.

It is inconceivable that agencies of the Federal Government would condone the use of substances which were unsafe. However, that is the tenor of Mr. Shibko's affidavit, wherein it is stated:

> The potential hazard from the use of these substances (sodium nitrate and sodium nitrite) in curing some meats is that the nitrates may result in the formation of chemical substances known as nitrosamines which are known to cause cancer in experimental animals.

Mr. Shibko's conclusion is paradoxical in view of the approval by both the Food and Drug Administration and the Department of Agriculture of the use of sodium nitrate and sodium nitrite. Since the use to which Petitioner puts

said products is identical to the use which has been approved by the Department of Agriculture, the District Court's conclusion rejecting the use of sodium nitrate and sodium nitrite must of necessity be in error.

The District Court, citing the absence of scientific testimony, concluded that sodium nitrate and sodium nitrite were not generally recognized as safe. However, the District Court neglected the remainder of 21 U. S. C. Section 321 (s) which states:

> . . . as having been adequately shown through scientific procedures (or in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food).

It is clear that both sodium nitrate and sodium nitrite were used in food products prior to January 1, 1958, and were clearly shown to be safe in experience based on common use in food. The necessity for the showing of scientific evidence on the use of sodium nitrate and sodium nitrite was not necessary in the case at bar.

Petitioner respectfully submits that in disregarding the clear statutory language of 21 U. S. C. Section 321 (s), the District Court's conclusion that sodium nitrate and sodium nitrite were not generally recognized as safe in conjunction with processing bison meat was in error.

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CONCLUSION

For the reasons aforesaid, Petitioner prays that a Writ of Certiorari be granted to review the judgment of the United States Court of Appeals for the Eighth Circuit.

Respectfully submitted,

ARTICLES OF FOOD, ETC., ROBERT NIELSEN d/b/a GRUMPY'S BUFFALO JERKY CO., Petitioner

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APPENDIX A

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEBRASKA

CIV. 77-0-349

UNITED STATES OF AMERICA,
Plaintiff,

vs.

Articles of food consisting of dark brown colored patties packaged and labeled as follows:

* * *

"BUFFALO JERKY * * *" etc.,
Defendant.

MEMORANDUM OPINION

(Filed July 12, 1978)

The United States of America brought this action seeking to condemn certain food substances pursuant to the Federal Food, Drug and Cosmetic Act, 21 U. S. C. § 301, et. seq. (hereafter referred to as "the Act"). The United States Marshal seized the substances identified in the complaint and the owner intervened to file a claim for return thereof. Each party filed a motion for summary judgment, the parties entered into a stipulation of facts (Filing No. 11) and the matter has been submitted for determination following a hearing.

At issue is a food substance made from the following ingredients: buffalo (bison) meat, textured vegetable protein, hydrolyzed vegetable protein, salt, spices, flavoring, sodium erythorbate, sodium nitrate, sodium nitrite, potas-

sium sorbate, water and monosodium glutamate (stipulation at Par. 5). These ingredients are combined into dark brown patties of meat packaged in jars and labeled as set out at Paragraph 3 of the stipulation.

The government seeks to have these food substances condemned pursuant to 21 U. S. C. § 334 which provides in part:

> (a)(1) Any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce . . . shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States . . . .

The parties have by their stipulation agreed that this court has jurisdiction over the instant action, that the food substances at issue are "articles of food" within the purview of 21 U. S. C. § 334, and in effect, that the food substances have been shipped in interstate commerce in their present condition. The questions presented for determination on summary judgment are whether the food substances are adulterated or misbranded within the meaning of the Act.

The government contends that the food items are adulterated within the meaning of 21 U. S. C. § 342 (a) (2) (c) because they contain sodium nitrate and sodium nitrite; that the food items are adulterated within the meaning of 21 U. S. C. § 342(b)(2) because certain plant proteins have been substituted in part for the principal ingredient—bison meat; and that the food items are misbranded within the meaning of 21 U. S. C. § 343 (i)(1). The government must

prevail on at least one of these allegations to permit the condemnation.

The government contends that the food substance at issue is adulterated within the meaning of 21 U. S. C. § 342 (a)(2)(C) which provides in relevant part:

> A food shall be deemed to be adulterated—if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title . . . .

"Food additive" as used in 21 U. S. C. § 342 is defined by 21 U. S. C. § 321 (s) as follows:

> The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—
>
> * * *
>
> (4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act (21 U. S. C. § 451 and the following) or the Meat Inspection Act of March 4, 1907, as amended and extended; . . . .

Title 21, United States Code, Section 348, provides in relevant part as follows:

> (a) A food additive shall, with respect to any particular use or intended use of such additives, be deemed

to be unsafe for the purposes of the application of clause (2)(C) of section 342 (a) of this title, unless—

> (1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or
>
> (2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

In determining whether the food substance at issue is adulterated within the meaning of 21 U. S. C. § 342 (a)(2)-(C), the court must first determine whether the food substance contained a "food additive" within the meaning of 21 U. S. C. § 321 (s). The definition of "food additive" consists of two elements: (a) the substance must become a component or otherwise affect the characteristics of the food and (b) the substance must lack general recognition among the experts as being safe under the conditions of its intended use. The parties have stipulated that the food substance does contain as component parts the items sodium nitrate and sodium nitrite. The affidavits submitted by the government adequately support the conclusion that the use of sodium nitrate and sodium nitrite in conjunction with processing bison meat is not generally recognized among experts as being safe. While the claimant points to other uses of sodium nitrate and sodium nitrite which have been recognized as being safe, these examples are not comparable to the use in this case and so do not refute the government's showing or raise a factual dispute as to whether the use of these products in bison meat is generally recognized as safe. Accordingly, the court finds that both elements of the definition of food additives have been met.

The claimant contends that these substances are approved for use under the Federal Meat Inspection Act, thus exempting them from the definition of food additives contained in 21 U. S. C. § 321 (s) and precluding a determination that the product is adulterated within the meaning of 21 U. S. C. § 342 (a)(2)(C). The government responds that this exception is inapplicable since the Meat Inspection Act applies only to meat food products which are defined by 21 U. S. C. § 601 (i), as:

> any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats .... This term as applied to food products of equines shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

Contrary to claimant's assertion that only added substance and not the meat to which it is added must be subject to the Meat Inspection Act, the exemption contained in 21 U. S. C. § 321 (s) provides that the use must be "in accordance with a sanction or approval granted pursuant to the Meat Inspection Act." The approval relied on by claimant is found at 9 C. F. R. § 318.7 (c)(10), which provides in part:

> ... the following substances may be added to products: common salt, approved sugars . . . sodium nitrate, sodium nitrite, potassium nitrate, potassium nitrite ...

"Products" as used in this regulation are defined at 9 C. F. R. § 301.2 (ww) as

> Any carcass, meat, meat byproduct, or meat food product, capable of use as human food.

The terms "carcass," "meat," "meat byproduct," and "meat food product" all are defined at 9 C. F. R. § 301-

(a)(ss) through (vv) in terms of cattle, sheep, swine, goats and equines only. Thus, the issue is whether bison meat is within the purview of the Meat Inspection Act when the term is not specifically included. Only if it is will the use of sodium nitrate and sodium nitrite here be "in accordance with a sanction or approval granted pursuant to the Meat Inspection Act."

The parties have referred the court to no reported cases regarding the applicability of the Meat Inspection Act to buffalo meat. An early Missouri case, *State v. Crenshaw*, 22 Mo. 457 (1856), does stand for the proposition that buffalo, although domesticated, are not cattle within the meaning of a statute making it a crime to "wilfully and maliciously kill, wound or maim any cattle of another." As the policies underlying the Missouri criminal statutes and the Meat Inspection Act are quite different, we do not consider this case to be controlling. We therefore, turn to the purpose and the language of the Federal Meat Inspection Act to resolve the issue.

The Meat Inspection Act is, by its very terms, designed to protect the health and welfare of consumers:

> by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged.
>
> 21 U. S. C. § 602.

As such the Meat Inspection Act is not intended to derogate from any authority conferred by the Federal Food, Drug, and Cosmetic Act. *See* 21 U. S. C. § 679. Rather, the Meat Inspection Act creates a separate area of concern—(meat and meat byproducts for human consumption) —over which the Department of Agriculture is given addi-

tional powers in the interest of protecting the public health and welfare.

The Meat Inspection Act specifically delineates the food products subject to its provisions, listing only foods derived from cattle, sheep, swine, goats and equines. Other food products are regulated under the Food, Drug and Cosmetic Act. In view of the safeguards of testing and regulation of ingredients set forth in the comprehensive regulations promulgated pursuant to the Food, Drug and Cosmetic Act, the court finds that food products derived from bison meat will be adequately regulated for the protection of the public health and welfare under either the Food, Drug and Cosmetic Act or the Meat Inspection Act. In the absence of a congressional determination to include bison meat within the more limited coverage of the Meat Inspection Act, this court is unwilling to judicially extend the provisions of the Meat Inspection Act to do so. Accordingly, the court finds that the government correctly seeks to apply the provisions of the Food, Drug and Cosmetic Act to the food products at issue in this case. Therefore, the exception to the definition of food additives contained in 21 U. S. C. § 321 (s) for substances used in accordance with a sanction or approval granted pursuant to the Meat Inspection Act is not applicable.

Having determined that sodium nitrate and sodium nitrite are food additives within the meaning of 21 U. S. C. § 342 (a)(2)(C), the court now turns to the question of whether or not these additives are "unsafe within the meaning of Section 348 of this Title." Under the provisions of Section 348, a use is deemed to be unsafe for purposes of the Act unless an exemption is granted by the Secretary of Health, Education and Welfare upon proper

application or unless the use is in accordance with a regulation prescribed by the Secretary. The language of the statute establishes a presumption that the food additives are unsafe unless one of the exceptions is established. The court has carefully examined the regulations promulgated by the Secretary but has been unable to identify any regulations which are applicable to the instant use of the food additives sodium nitrate and sodium nitrite. The claimant has failed to demonstrate either an exemption or investigative use or a regulation permitting such use. Accordingly, the court finds that the claimant's use of the food additives sodium nitrate and sodium nitrite are not approved by the Secretary and, therefore, are unsafe within the meaning of Section 348 of Title 21, United States Code.

Having determined that the food product at issue is a food which contains a food additive which is unsafe within the meaning of Section 348, the court now finds that this food product shall be deemed to be adulterated within the meaning of 21 U. S. C. § 342 (a)(2)(C) and subject to seizure pursuant to 21 U. S. C. § 334. As a sufficient basis exists pursuant to 21 U. S. C. § 342 (a)(2)(C) for the condemnation of the food products seized by the United States Marshal, this court does not address the alternative allegations of adulteration and misbranding which have been argued by the government.

A separate decree will be entered this day denying claimant's motion for summary judgment, granting summary judgment for the plaintiff, and decreeing the food products at issue to be adulterated within the meaning of the Food, Drug and Cosmetic Act and subject to condemnation. Within twenty days following entry of this order, the parties shall submit to the court for its approval a proposed method for disposition of the condemned goods. The costs of this action shall be taxed against the claimant in accordance with 21 U. S. C. § 334 (e).

By the Court:

/s/ Albert G. Schatz
Judge, United States District Court

ORDER

(Filed July 12, 1978)

In accordance with the memorandum opinion entered this date,

IT IS HEREBY ORDERED that claimant's motion for summary judgment (Filing No. 6) is denied.

IT IS FURTHER ORDERED that plaintiff's motion for summary judgment (Filing No. 10) is sustained.

IT IS DECREED that the food products at issue are adulterated and are subject to condemnation. The parties shall submit to the court within twenty (20) days a proposed method for disposition of the condemned goods.

IT IS FURTHER ORDERED that costs of this action are to be taxed against the claimant.

By the Court:

/s/ Albert G. Schatz
Judge, United States District Court

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No. 78-1643

UNITED STATES OF AMERICA,

Appellee,

vs.

ARTICLES OF FOOD, ETC., ROBERT NIELSEN d/b/a GRUMPY'S BUFFALO JERKY CO.,

Appellant.

Appeal from the United States District Court for the District of Nebraska

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Submitted: January 12, 1979

Filed: January 16, 1979

Before ROSS and McMillian, Circuit Judges, and VAN SICKLE, District Judge.*

PER CURIAM.

In this appeal Robert Nielsen d/b/a Grumpy's Buffalo Jerky Co. seeks review and reversal of an order of the district court which concluded that the food product buffalo jerky was adulterated within the meaning of 21 U. S. C. § 342 and subject to seizure pursuant to 21 U. S. C. § 334

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*The Honorable BRUCE M. VAN SICKLE, United States District Judge for the District of North Dakota, sitting by designation.

due to the fact that the product contained an unsafe "food additive" within the meaning of 21 U. S. C. § 348.

We have carefully considered the arguments which appellant has made, including the argument that a substance cannot be declared an unsafe "food additive" in one context, but acceptable in another use, and the argument that the Meat Inspection Act, which approves certain uses of sodium nitrates and sodium nitrites, should be construed to include "buffalo" meat within its terms, although buffalo is not expressly listed.

After reading the appellant's citations of authority, and reviewing the affidavits submitted, we conclude that the district court did not err in its well-reasoned opinion and affirm on the basis of that opinion.

The judgment is affirmed.

A true copy.

Attest:

Clerk, U. S. Court of Appeals,
Eighth Circuit.

[Not to be published.]

APPENDIX C

FOOD, DRUG AND COSMETIC ACT

21 U. S. C. Sec. 301, et. seq.

21 U. S. C. Sec. 321 (s)

The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

* * *

(4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act (21 U. S. C. Sec. 451 and the following) or the Meat Inspection Act of March 4, 1907, as amended and extended; . . .

21 U. S. C. Sec. 342 (a)(2)(C)

A food shall be deemed to be adulterated—if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title . . .

21 U. S. C. Sec. 348

(a) A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2)(C) of section 342 (a) of this title, unless—

(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

MEAT INSPECTION ACT

21 U. S. C. Sec. 601 et. seq.

21 U. S. C. Sec. 601 (J)

The term "meat food product" means any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any *cattle*, *sheep*, *swine*, or *goats* ****. This term as applied to food products of *equines* shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

21 U. S. C. Sec. 601 (m)(2)(C)

(m) The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances: . . .

(2) (C) if it bears or contains any food additive which is unsafe within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act . . .

9 C. F. R. Sec. 301.2

(rr) *Livestock.* Cattle, sheep, swine, goat, horse, mule or other equine.

(ss) *Carcass.* All parts, including viscera, of any slaughtered livestock.

(ww) *Product.* Any carcass, meat, meat byproduct, or meat food product, capable of use as human food.

9 C. F. R. Sec. 318.7 (c)(10)

. . . the following substances may be added to products: common salt, approved sugars . . . sodium nitrate, sodium nitrite, potassium nitrate, potassium nitrite . . .

21 C. F. R. Sec. 172.170

The food additive sodium nitrate may be safely used in or on specified foods in accordance with the following prescribed conditions:

(a) It is used or intended for use as follows: . . .

21 C. F. R. Sec. 172.175

The food additive sodium nitrite may be safely used in or on specified foods in accordance with the following prescribed conditions:

(a) It is used or intended for use as follows: . . .

Supreme Court, U. S.
FILED
JUN 19 1979
MICHAEL RODAK, JR. CLERK

No. 78-1725

In the Supreme Court of the United States

OCTOBER TERM, 1978

ARTICLES OF FOOD, ETC., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

MEMORANDUM FOR THE UNITED STATES IN OPPOSITION

WADE H. MCCREE, JR.
Solicitor General
Department of Justice
Washington, D.C. 20530

In the Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-1725

ARTICLES OF FOOD, ETC., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

MEMORANDUM FOR THE UNITED STATES IN OPPOSITION

Petitioners contend that the courts below erred in holding that sodium nitrate and sodium nitrite, when used as components in a processed buffalo meat product ("Buffalo Jerky"), are unsafe food additives within the meaning of 21 U.S.C. 321(s) and 348(a).

1. The United States filed a complaint seeking condemnation of certain articles of food (branded as "Buffalo Jerky") pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.* The complaint alleged that "Buffalo Jerky" is adulterated within the meaning of 21 U.S.C. 342(a)(2)(C) because it contains sodium nitrate and sodium nitrite, which are unsafe food additives as defined under 21 U.S.C. 321(s) and 348(a).

The district court granted the government's motion for summary judgment (Pet. App. 1-9). It held that sodium nitrate and sodium nitrite are food additives within the

meaning of 21 U.S.C. 321(s) on the basis of a stipulation that they are components of "Buffalo Jerky" and uncontroverted affidavits demonstrating that they are not generally recognized among experts as safe when used to process buffalo meat (Pet. App. 4).[1] The district court also concluded that the Federal Meat Inspection Act, 21 U.S.C. 601 *et seq.*, does not authorize the use of such food additives since that statute has no application to buffalo meat (*id.* at 5-7). In light of the fact that "Buffalo Jerky" contains food additives that are not approved under FDA exemptions or regulations, the district court held that the product was adulterated within the meaning of 21 U.S.C. 342(a)(2)(C) (*id.* at 7-8). The court of appeals affirmed (*id.* at 10-11).

2. Petitioner contends (Pet. 7-11) that the district court erred in concluding that sodium nitrate and sodium nitrite are "food additives." Petitioner also contends that the question whether a particular substance is an "additive" cannot depend on the nature of the food to which it is added (Pet. 10).

However, 21 U.S.C. 321(s) defines the term "food additive" as follows:

> [A]ny substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food * * * if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) *to be safe under the conditions of its intended use* * * * [emphasis supplied].

Thus, a substance that is a food component is an "additive" subject to the provisions of the Act unless it is generally recognized to be safe under the conditions of its intended use. For this reason, a substance may be deemed to be an "additive" in certain uses but not in others, depending on the amount of the substance that is introduced and the nature of the food that is treated.[2] On the basis of uncontroverted affidavits, the district court properly found that sodium nitrate and sodium nitrite are not generally recognized as safe when used to cure buffalo meat. That factual finding was a sufficient predicate for the determination that sodium nitrite and sodium nitrate constitute "additives" within the meaning of the Act. The court of appeals affirmed this factual determination, and there is no need for further review in this Court. *Berenyi* v. *Immigration Director*, 385 U.S. 630, 635 (1967).[3]

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[1]The parties stipulated that buffalo (bison) meat is an ingredient in "Buffalo Jerky" (Pet. 4). The affidavits filed by the government established that sodium nitrate and sodium nitrite pose potential health hazards when used to cure various kinds of meat because they can cause the formation of chemical substances (nitrosamines) which are known to cause cancer in experimental animals (Pet. 15).

[2]This principle is illustrated by the FDA's regulations, which recognize that sodium nitrate and sodium nitrite are safe only when used in certain quantities in curing certain meat products. See 21 C.F.R. 172.170; 21 C.F.R. 172.175.

[3]Food "additives" are conclusively deemed to be "unsafe" under 21 U.S.C. 348 unless an exemption has been granted by the Secretary of Health, Education, and Welfare or a regulation has been promulgated permitting their use. No such exemption or regulation exists in this case (Pet. App. 7-8).

3. Contrary to petitioner's assertion (Pet. 11-14), buffalo meat treated with sodium nitrate and sodium nitrite is not subject to the provisions of the Federal Meat Inspection Act.[4] The Federal Meat Inspection Act is concerned only with "meat food products," which it defines in the following limited terms (21 U.S.C. 601(j); emphasis supplied):

> [A]ny product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any *cattle, sheep, swine, or goats* * * *. This term as applied to food products of *equines* shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

As the district court noted, buffalo or bison meat is not included within this definition (Pet. App. 6). The definition includes only ranch and farm livestock, customarily used in the commercial production of meat products.[5] In light of the fact that the Department of Agriculture has never interpreted the Meat Inspection Act

[4]If the sale of buffalo (bison) meat cured with sodium nitrate and sodium nitrite was "in accordance with a sanction or approval" granted by the Department of Agriculture under the Meat Inspection Act, 21 U.S.C. 601 *et seq.*, sodium nitrite and sodium nitrate would be exempt from the definition of food "additive" under the Federal Food, Drug, and Cosmetic Act. See 21 U.S.C. 321(s)(4).

[5]Congress' failure to include buffalo or bison meat in the Federal Meat Inspection Act of 1907 is not surprising. By 1907 the American buffalo was nearly extinct. A census of the buffalo herd in 1903 showed that only 34 wild bison were left in the United States. The rest of the surviving buffalo were kept in zoos. See 4 *Encyclopaedia Britannica* ("Bison") (1911).

to include buffalo meat products, the district court was clearly correct in declining to rewrite the statute to include a variety of meat not covered by its literal terms.[6]

It is therefore respectfully submitted that the petition for a writ of certiorari should be denied.

WADE H. MCCREE, JR.
Solicitor General

JUNE 1979

[6]Moreover, even assuming that buffalo meat should be viewed as a meat product subject to the Federal Meat Inspection Act, petitioner wholly failed to show that "Buffalo Jerky," processed with sodium nitrate and sodium nitrite, was "in accordance with a sanction or approval" of the Department of Agriculture. The Department's regulations do allow use of sodium nitrate and sodium nitrite as curing agents, but only in limited quantities. See 9 C.F.R. 318.7(c). Petitioners made no showing that "Buffalo Jerky" contains sodium nitrate and sodium nitrite in legally permissible amounts, and thus failed to show the availability of an "approval" under the Meat Inspection Act that would justify an exemption from the coverage of the Food, Drug, and Cosmetic Act. That burden of demonstration rested on petitioners. See *United States* v. *1,048,000 Capsules, More or Less etc.*, 347 F. Supp. 768, 770 (S.D. Tex. 1972), aff'd, 494 F. 2d 1158 (5th Cir. 1974); *United States* v. *An Article of Drug "Bentex Ulcerine"*, 469 F. 2d 875, 878 (5th Cir. 1972), cert. denied, 412 U.S. 938 (1973).